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Editorial Comment

Structural Valve Deterioration at 5 Years of TAVR Versus SAVR: Half Full or Half Empty?*

Eric Van Belle MD, PhD, Cédric Delhaye MD, Flavien Vincent MD, PhD

Refers to

Structural Deterioration of Transcatheter Versus Surgical Aortic Valve Bioprostheses in the PARTNER-2 Trial

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Philippe Pibarot, Julien Ternacle, Wael A. Jaber, Erwan Salaun, Abdellaziz Dahou, Federico M. Asch, Neil J. Weissman, Leonardo Rodriguez, Ke Xu, Mohamed-Salah Annabi, Ezequiel Guzzetti, Jonathan Beaudoin, Mathieu Bernier, Jonathon Leipsic, Philipp Blanke, Marie-Annick Clavel, Erin Rogers, Maria C. Alu, Pamela S. Douglas, Raj Makkar, D. Craig Miller, Samir R. Kapadia, Michael J. Mack, John G. Webb, Susheel K. Kodali, Craig R. Smith, Howard C. Herrmann, Vinod H. Thourani, Martin B. Leon, Rebecca T. Hahn

Key Words

aortic stenosis

bioprosthetic valve

Doppler echocardiography

structural valve deterioration

transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) is a widespread treatment for aortic stenosis (AS) as randomized trials have provided outcomes that are compelling compared with surgical aortic valve replacement (SAVR) on hard clinical endpoints, regardless of the surgical risk, at short follow-up (for low risk) or 5-year follow-up (1).

Like the surgically implanted bioprosthetic surgical heart valve (SHV), several mechanisms can affect the performance of a transcatheter bioprosthetic heart valve (THV) over time, as reported by the following Valvular Academic Research Consortium (VARC)-3 classifications of bioprosthetic dysfunctions: 1) structural valve deterioration (SVD), defined as irreversible morphological changes of the valve; 2) reversible valve deterioration such as valve thrombosis or endocarditis; and 3) nonstructural valve deterioration: mainly paravalvular regurgitation (PVR) and prosthesis-patient mismatch (PPM) (2,3) (Figure 1).

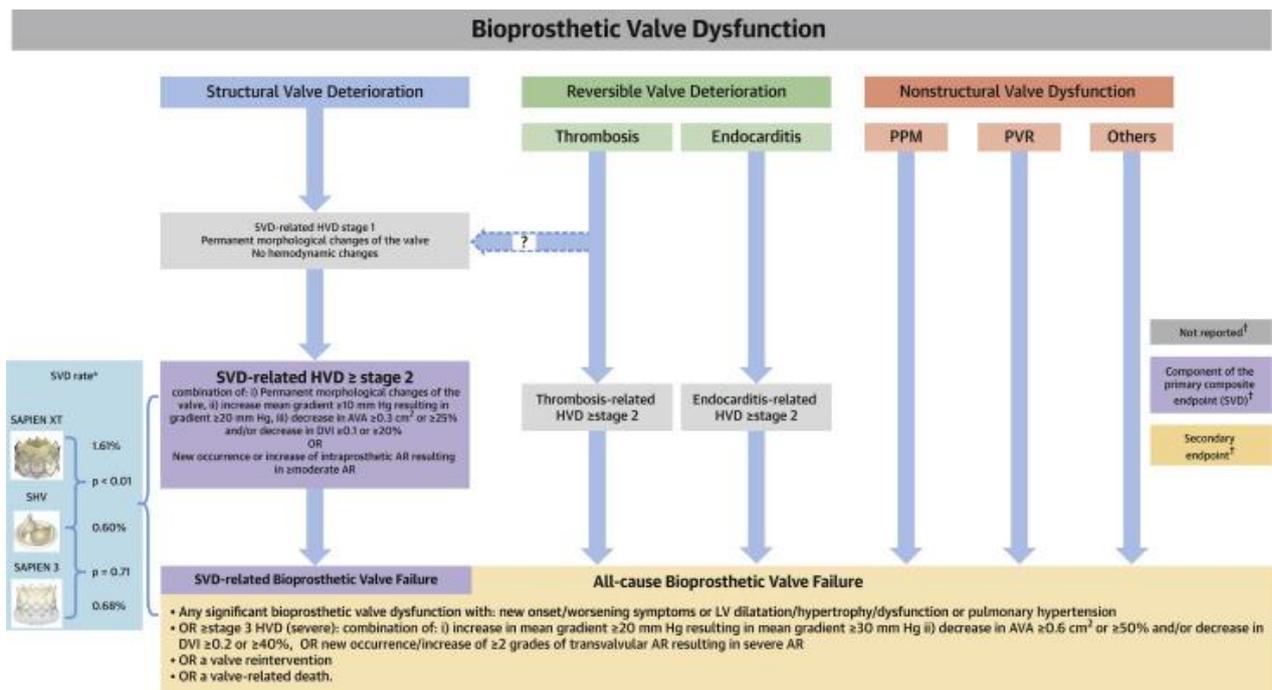


Figure 1. Structural Valve Degeneration in the Global Evaluation of a Bioprosthetic Valve Dysfunction Classification According to VARC-3

*SVD rate in Pibarot et al. (4) was defined as a composite endpoint of SVD-related HVD ≥ stage 2 or SVD-related bioprosthetic valve failure and was reported as exposure-adjusted incidence rate (per 100 patient-years). †Refer to endpoint reported in the Pibarot et al. (4) study. AVA = aortic valve area; DVI = Doppler velocity index; HVD = hemodynamic valve deterioration; PPM = patient-prosthesis mismatch; PVR = paravalvular regurgitation; SVD = structural valve deterioration; VARC = Valvular Academic Research Consortium.

A bioprosthetic valve failure (BVF) occurs either when 1 of the 3 above-mentioned categories induces a severe and permanent hemodynamic valve deterioration (HVD) or when it is associated with new symptoms, a valve-related reintervention, or a valve-related death. In this issue of the *Journal*, Pibarot et al. (4) compared the occurrence of 1 mechanism of valve dysfunction (i.e., the SVD of balloon-expandable valve of a second [SAPIEN-XT; Edwards Life Sciences, Irvine, California] and third [SAPIEN-3] generation vs. SHV at mid-term [5 years]) (4).

The comparison between SAPIEN-XT (n = 774) and SHV (n = 664) was performed using the intermediate-risk Placement of Aortic Transcatheter Valves 2 cohort A (PARTNER-2A) randomized study (5). The comparison between SAPIEN-3 (n = 891) and SHV was done through the prospective PARTNER-2 SAPIEN-3 intermediate-risk registry (6) using propensity-score methods.

The authors used a modified VARC-3 definition of SVD as the primary endpoint: the composite of SVD-related HVD ≥stage 2 (combination of hemodynamic and valve morphological changes) or SVD-related BVF rates and reported as exposure-adjusted incidence rate (per 100 patient-years). All-cause BVF was a secondary endpoint (Figure 1). The first finding of this study was the inferior durability of SAPIEN-XT versus SHV with a 2.5-fold rate of SVD ($1.61 \pm 0.24\%$ vs. $0.63 \pm 0.16\%$, respectively; $p < 0.01$) leading to a 5-year cumulative SVD rate of 9.5% versus 3.5%, respectively ($p \leq 0.001$). Then, the authors demonstrated that the transition to SAPIEN-3 increased THV durability with a 2-fold SVD ($p = 0.0001$) and SVD-related BVF rate reduction ($p = 0.03$) versus SAPIEN-XT. This put SAPIEN-3 durability in the same league as SHV, as demonstrated by the lack of differences

in the rates of SVD ($0.68 \pm 0.18\%$ vs. $0.60 \pm 0.17\%$, respectively; $p = 0.71$) and SVD-related BVF ($0.29\% \pm 0.12\%$ vs. $0.14\% \pm 0.08\%$, respectively; $p = 0.25$).

However, a higher risk of all-cause BVF was observed with SAPIEN-3 than SHV ($0.50 \pm 0.12\%$ vs. $0.21 \pm 0.08\%$, respectively; $p = 0.004$), driven by more frequent valve reintervention in SAPIEN-3 ($n = 17$ of 19) than SHV ($n = 6$ of 8). In SAPIEN-3 reinterventions were mainly due to PVR (65%) and predominantly managed percutaneously by transcatheter aortic valve in transcatheter aortic valve (TAV-in-TAV) (66%) with 0% mortality, whereas reinterventions in SHV were predominantly treated with redo surgery (83%), mainly for endocarditis (67%) with a high 30-day mortality (50%).

In most SAVR studies, SVD was primarily based on the occurrence of reintervention for BVF, which reflects more our capacity to identify and will for treating a valve dysfunction than an objective endpoint on durability itself, as nicely illustrated by Pibarot et al. (4). It is indeed remarkable that, although endocarditis is known to occur evenly in TAVR and SAVR (7), it represented one-half of the reinterventions after SAVR but none after TAVR, and that although PVR is much less frequent in SAPIEN-3 than in SAPIEN-XT, more SAPIEN-3 recipients had reintervention for PVR. By focusing on SVD defined by echocardiographic changes and assessed by an independent core laboratory, the study is pivotal for our understanding of valve durability through a reproducible and less biased outcome (4).

The authors chose to use the refined VARC-3 definition of SVD that required the availability of a post-procedural echocardiography. This has the main advantage of properly differentiating SVD from PPM. The counterpart is that 22% of patients were not analyzed, which reduces the representativity of the analysis population. Fortunately, the all-cause BVF rate (analyzed in the overall population) was consistent with the SVD rate.

This study addressed only SVD and did not provide a complete spectrum of the THV functioning over time that should be assessed globally through PVR, PPM, thrombosis, and endocarditis (Figure 1). PPM seems more frequent with SHV (Supplemental Table 3 [4]), and the occurrence of PVR (5,6) and endocarditis (7) has already been reported elsewhere and showed grossly a superiority of SAVR for the former and equivalence of both for the latter. The true clinical impact of THV thrombosis is unknown but could be more frequent after TAVR than after SAVR and be a trigger for SVD. The recent PARTNER-3 echocardiographic data corroborated these concerns, observing leaflet thrombosis as the main cause of HVD at 1 year (8). Because neither the clinically significant HVD-related thrombosis nor the rate of SVD preceded by thrombosis were reported in this study (except if they led to BVF), it remains a nonelucidated issue of THV that needs dedicated studies.

Finally, these results relate only to intermediate-risk patients. Whether SHV and SAPIEN-3 will achieve the same durability in lower-risk patients is unknown as, similar to the present study, younger age has been repeatedly associated with higher risk of SVD.

Early in 2020, the PARTNER-2A randomized trial reported similar incidence at 5-year of the composite endpoint of mortality or disabling stroke between SAPIEN-XT and SAVR (9).

However, a landmark analysis beyond 2 years showed a higher late mortality with TAVR.

The study by Pibarot et al. (4) provides one of the probable reasons: the limited and insufficient durability of SAPIEN-XT versus SAVR.

Conversely, TAVR with SAPIEN-3 also evaluated in intermediate-risk population in the PARTNER-2 SAPIEN-3 registry achieved similar outcomes versus SAVR during the 5 years of follow-up without late mortality increase (10). The present study demonstrating the low and similar SVD rates of SAPIEN-3 versus SHV enhance that the improvement of THV durability was directly associated with better mid-term clinical outcomes.

The message of a higher risk of BVF (\approx reintervention) with SAPIEN-3 than SHV may seem worrying, but it may also result in raising awareness of the deleterious impact of PVR (11).

Improvements in the prevention of PVR (newer device, high THV positioning, computed

tomography fusion) should help to reduce the need for TAV-in-TAV or surgical reinterventions in the near future.

Finally, the present data are also important for delineating the respective role of TAVR and SAVR in the lifetime management of patients, particularly for the youngest with a long life expectancy. Keeping in mind that both modalities have durability issues of the same order of magnitude at 5 years (with SAPIEN-3), the timely use of the 2 techniques along the patient's lifespan is crucial. However, given the paucity of data for outcomes of SAVR after THV, long-term durability in low-risk patients and coronary issues after TAV-in-TAV, it seems too early to recommend TAVR for all the youngest and lower risk patients.

Conversely, the body of favorable data for TAVR in addition to the present reassuring data for TAVR durability support the fact that SAVR should not be proposed as the go-to treatment for all young candidates for a bioprosthetic valve.

The clinical pathway for aortic stenosis should now make up a valve and vascular computed tomography assessment and a clinical evaluation with both interventional structural cardiologists and cardiothoracic surgeons to predict as accurately as possible the outcomes of the 2 techniques and individualize the treatment.

Overall, a lifetime plan of care should be discussed with the patient to put in perspective that both techniques are complementary and could be required during his or her lifespan, in the same way that percutaneous coronary intervention and coronary artery bypass graft surgery can be used at different moments for a given patient. Now the ball is in the heart team's court to use both techniques in a comprehensive manner for the greatest benefit of the patients.

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